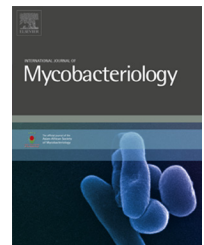


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Bedaquiline in the multidrug-resistant tuberculosis treatment: Belarus experience

Alena Skrahina^{a,*}, Hennadz Hurevich^a, Dennis Falzon^b, Liudmila Zhilevich^c, Valiantsin Rusovich^d, Masoud Dara^e, Svetlana Setkina^f

^a Republican Scientific and Practical Centre for Pulmonology and Tuberculosis, Minsk, Belarus

^b Global Tuberculosis Programme, World Health Organisation, Geneva, Switzerland

^c General Directorate of Medical Care, Ministry of Health, Minsk, Belarus

^d Country Office, World Health Organisation, Minsk, Belarus

^e Regional Office for Europe, World Health Organisation, Copenhagen, Denmark

^f Centre for Examinations and Tests in Health Care, Minsk, Belarus

ARTICLE INFO

Article history:

Received 27 October 2016

Accepted 6 November 2016

Available online xxx

Keywords:

Anti-TB drug

Bedaquiline

Multidrug and extensively drug-resistant tuberculosis

Multidrug-resistant tuberculosis

ABSTRACT

Background/objective: Outcomes of treatment for multidrug-resistant tuberculosis (MDR-TB) remain poor worldwide. Among patients with MDR-TB in Belarus who started treatment in 2012, only 54% completed it successfully, with treatment failure reported in 22% of the patients; additionally, 11% died and 13% were lost to follow-up or remained unevaluated. In Belarus, to improve outcomes, bedaquiline was introduced in MDR-TB treatment in June 2015. The national TB program developed measures to monitor safety and effectiveness of bedaquiline-containing regimens in line with the World Health Organization recommendations.

Methods: After enrollment of patients, clinical, radiological, laboratory, and microbiological data were carefully collected at start, during treatment, and at follow-up. A total of 197 patients were enrolled: male, 140 (71%); female, 57 (29%); new TB cases, 83 (42%); previously treated, 114 (58%); extensively drug-resistant-TB (XDR-TB), 128 (65%), pre-XDR-TB (fluoroquinolone resistant), 34 (17%), pre-XDR-TB (injectables resistant), 25 (13%), and other MDR-TB cases, 10 (5%).

Results: According to the intermediate analysis, 186 patients currently are continuing with the treatment, two patients died, and nine patients were lost to follow-up. Sputum culture conversion were observed in 186 patients (94%) at 6 months and one (0.5%) of these 197 patients started treatment; six patients (3%) remain sputum culture positive. The safety data were as follows: 135 patients (68%) experienced metabolism and nutrition disorders (hyperuricemia being the most common), 127 patients (64%) experienced hepatobiliary disorders (hepatic functions abnormality being the most common), 93 patients (47%) experienced electrolyte disorders (hypomagnesemia being the most common), 80 patients (41%) experienced cardiac disorders (abnormal electrocardiogram and arrhythmia being the most common), 68 patients (35%) experienced gastrointestinal system disorders (nausea, vomiting, and abdominal pain being the most common disorders), 54 patients (27%) experienced blood and the lymphatic system disorders (low platelet count being the most common), 42 patients (21%) experienced renal and urinary disorders (creatinine clearance

* Corresponding author.

E-mail address: alena_skrahina@tut.by (A. Skrahina).

Peer review under responsibility of Asian African Society for Mycobacteriology.

<http://dx.doi.org/10.1016/j.ijmyco.2016.11.014>

decrease being the most common), 40 patients (20%) experienced nervous system disorders (headache, dizziness, and paresthesia being the most common ones), 36 patients (18%) experienced skin and subcutaneous tissue disorders (rash and pruritus being the most common), 35 patients (17%) experienced ear and labyrinth disorders (tinnitus and decreased hearing being the most common ones), 32 patients (15%) experienced psychiatric disorders (insomnia being the most common disorder), and 30 patients (14%) experienced infections and infestations (candidiasis being the most common). The most adverse events were mild or moderate in severity and reversible. One death was possibly related to MDR-TB therapy.

Conclusion: Our interim results on safety and effectiveness of bedaquiline-containing regimens in multidrug and extensively drug-resistant tuberculosis (M/XDR-TB) patients are encouraging. They will add value to understanding role and place of this new anti-TB drug in M/XDR-TB treatment.

Conflicts of interest

The authors have no conflicts of interest to declare.